

ສາທາລະນະລັດ ປະຊາທິປະໄຕ ປະຊາຊົນລາວ ສັນຕິພາບ ເອກະລາດ ປະຊາທິປະໄຕ ເອກະພາບ ວັດທະນະຖາວອນ

> Lao People's Democratic Republic Peace Independence Democracy Unity Prosperity

# ກົດໝາຍ ວ່າດ້ວຍຄວາມປອດໄພ ດ້ານເຕັກໂນໂລຊີ ຊີວະພາບ

# **Biotechnology Safety Law**

ຈັດພິມໂດຍ: ສະຖາບັນນິເວດວິທະຍາ ແລະ ເຕັກໂນໂລຊີ ຊີວະພາບ, ກະຊວງວິທະຍາສາດ ແລະ ເຕັກໂນໂລຊີ ສົມທິບກັບ ກົມໂຄສະນາອົບຮົມກົດໝາຍ, ກະຊວງຍຸຕິທຳ Printed by: Biotechnology and Ecology Institute Ministry of Science and Technology In Coordination with Dissemination Law Department Ministry of Justice

# 2014 (ສະຫງວນລິຂະສິດ)



Lao People's Democratic Republic Peace Independence Democracy Unity Prosperity

# Unofficial Translation Biotechnology Safety Law



# LAO PEOPLE'S DEMOCRATIC REPUBLIC Peace Independence Democracy Unity Prosperity

National Assembly

No. 017 /NA

# **RESOLUTION** Of the **NATIONALASSEMBLY** Of the **LAO PEOPLE'S DEMOCRATIC REPUBLIC** On the Approval of Biotechnology Safety Law

Pursuant to Article 53, Paragraph 2 of the Constitution and Article 3, Paragraph 1 of the National Assembly Law of the Lao People's Democratic Republic regarding the rights and duties of the National Assembly;

After the 6<sup>th</sup> ordinary session of the VII National Assembly Congress, wide studies and consideration were undertaken and agreement was reached on the content of Biotechnology Safety Law in resolution at afternoon session of 18 December 2013.

# The session agreed:

Article 1. The Biotechnology Safety Law was approved by majority vote.

Article 2. This Resolution shall enter into force on the date it is signed.

Vientiane, 18 December 2013 **President of the National Assembly** *[Seal and Signature]* 

Pany YATHOTOU



# LAO PEOPLE'S DEMOCRATIC REPUBLIC Peace Independence Democracy Unity Prosperity

President's Office

No. 058 /PO Vientiane, 28 January 2014

# DECREE

#### Of the

# PRESIDENT

# Of the

# LAO PEOPLE'S DEMOCRATIC REPUBLIC On the Promulgation of Biotechnology Safety Law

-----

- Pursuant to Paragraph 1, Article 67, Chapter VI of the Constitution of the Lao People's Democratic Republic;

- Pursuant to the Resolution of the National Assembly No. 017/NA, dated 18 December 2013;

- Pursuant to the Request Letter of the Standing Committee of the National Assembly No. 08/SCNA, dated 23 January 2014.

# The President of the Lao People's Democratic Republic Issue a Decree:

Article 1. Promulgate the Biotechnology Safety Law

Article 2. This Presidential Decree is effective from the date of its signing

# President of the Lao People's Democratic Republic

[Seal and Signature]

Choummaly SAYASONE

# Contents

	Pages
Part I General Provisions	1
Article 1 Objectives	1
Article 2 Biotechnology safety	
Article 3 Explanation of terms	
Article 4 State policy on biotechnology safety	
Article 5 Principles on biotechnology safety works	
Article 6 Scope of application	
Article 7 International cooperation	
Part II Biotechnological Works	4
Section 1 Types of Research and Development	
Article 8 Biotechnological research and development	
Article 9 Types of biotechnological research and developmer	
Article 10 Basic scientific research and development	
Article 11 Applied scientific research and development	
Article 12 Research on biotechnological risk	
Section 2 Research and Development	5
Article 13 Research and development priorities	
Article 14 Biotechnology in genetic resources	
Article 15 Biotechnology in agriculture and forestry	6
Article 16 Biotechnology in health	6
Article 17 Biotechnology in the processing industry	7
Article 18 Biotechnology in the Environment	7
Section 3 Use of Biotechnology	7
Article 19 Use of biotechnology	
Article 20 Types of biotechnology use	7
Section 4 Protection of Research and Development	
Results	8
Article 21 Biotechnology patents	8
Article 22 Traditional knowledge	8

Article 23 Human cloning	8
Article 24 Access to and benefit sharing of genetic resources	9
Article 25 Confidential information.	9
Part III Biotechnology Risk Analysis	0
Article 26 Biotechnology risk analysis	
Article 27 Handling request and risk Analysis	
Article 28 Technical regulations on risk analysis	
Section 1 Biotechnology Risk Assessment	10
Article 29 Biotechnology risk assessment	
Article 30 Risk assessment process	
Article 31 Objectives of risk assessment	
Section 2 Biotechnology Risk Management	11
Article 32 Biotechnology risk management	
Article 33 Basic principles of risk management	
Article 34 Approaches to risk assessment management	
Section 3 Biotechnology Risk Communication	13
Article 35 Biotechnology risk communication	
Article 36 Agreement and communication on agreement results	
Article 37 Agreement revision	
Article 38 Monitoring and provision of updated information	16
Article 39 Proposal of instructions	16
Part IV Human Resource Development and Public	
Participation	17
Article 40 Human resource development	.17
Article 41 Specialists	17
Article 42 Public participation	17
Article 43 Information exchange of researches	18
Article 44 Biotechnology safety clearing house	18
Part V Prohibitions	
Article 45 General prohibitions	18

Article 46 Prohibitions for Concerned Government Officials	18
Article 47 Restrictions on entrepreneurs	19
Part VI Dispute Resolution	19
Article 48 Forms of dispute resolution	
Article 49 Settlement through compromise	
Article 50 Settlement by administrative means	
Article 51 Settlement by the Office of economic dispute	
resolution	20
Article 52 Bringing a suit to a court of justice	20
Article 53 Settlement by international arbitration	
Part VII The Committee for Biotechnology Safety	
Administration	20
Article 54 The Committee for Biotechnology Safety	
Administration	20
Article 55 Location and functions of the National Committee for	r
Biotechnology Safety	20
Article 56 Structure of the National Committee for	
Biotechnology Safety	21
Article 57 Rights and Duties of the National Committee for	
Biotechnology Safety	21
Article 58 Location and functions of the Technical Coordination	l
Committee	22
Article 59 Structure of the Technical Coordination Committee	22
Article 60 Rights and Duties of the Technical Coordination	
Committee	23
Part VIII Administration and Inspection	23
Section 1 Administration of Biotechnology	
Safety Tasks	23
Article 61 Administrative organization	
Article 62 Rights and Duties of the Ministry of Science and	
Technology	24
Article 63 Rights and Duties of the Department of Science	
and Technology at Capital and Provinces	25

Article 64 Rights and Duties of District and Municipal Science	
and Technology Offices	26
Article 65 Rights and Duties of other Sectors	27

Section 2 Inspection of Biotechnology Safety	Tasks27
Article 66 Inspection Agency	
Article 67 Contents of inspection	
Article 68 Elements of inspection	

# Part IX Policies on Performance Generators and

Measures for Violators	
Article 69 Policies on performance generators	
Article 70 Measures on violators	29
Article 71 Measures of reprimand	29
Article 72 Measures of punishment	29
Article 73 Measures of fines	29
Article 74 Civil measures	30
Article 75 Criminal measures	30
Article 76 Measures of additional punishment	
_	

Part X Final Provisions	30
Article 77 Organizational implementation	30
Article 78 Effective date	31



# Lao People's Democratic Republic Peace Independence Democracy Unity Prosperity

-----

National Assembly

No. 39 /NA Vientiane Capital, Dated 18 December, 2013

# **Unofficial Translation**

# **Biotechnology Safety Law**

# Part I General Provisions

# **Article 1 Objectives**

This law defines the principles, regulations and measures on management and monitoring of biotechnology safety to ensure safety in research, development, handling, movement, and the use of Genetic Modified Organisms (GMOs) resulting from the use of biotechnology, which may result in having negative impacts on conservation and sustainable use of biodiversity, with a focus on the limitation and reduction of risks to the life and health of human beings, animals, plants and the environment that can be linked at the regional and international levels, and which contribute to national socio-economic development.

# Article 2 Biotechnology safety

Biotechnology safety guarantees the limitation and reduction of risks caused by GMOs to the life and health of human beings, animals, plants, the environment, and socio-economic development according to the results of biotechnological science-based risk analysis.

# Article 3 Explanation of terms

The definitions of terms used in this law are as follows:

- 1. **Biotechnology** refers to the use of the body of scientific knowledge on biological systems or living components to create or modify a product and a specific manufacturing process;
- 2. **Body of knowledge** refers to systems of knowledge and understanding regarding research, development and use of science;
- 3. **Biological** refers to things related to living organisms which display an altered nature or altered characteristics of biodiversity;
- 4. **Biodiversity** refers to the variety of plants, animals and microbes found in nature;
- 5. Genetic resource refers to biological resources which can transfer the genetic code that contains the basic characteristics of living organisms within a specific ecological area;
- 6. **Gene** refers to the basic characteristics of living organisms; it is a code used for the inheritance or transmission of characteristics from one generation to another;
- 7. **Ecology** refers to both the positive and negative relationships between living organisms and nonliving organisms existing in nature;
- 8. Genetic Modified Organisms (GMOs) refers to living organisms created from modified existing genetic characteristics or creating new genetic characteristics by applying techniques and the cell fusion;
- 9. **Traditional knowledge** refers to the knowledge of people which has been inherited traditionally and culturally for a long time through records or other referential evidence;
- 10. **Contained use** refers to an operation or activity whose connection shall be limited, so as to prevent the impact of GMOs on the external environment and world population;
- 11. **Import for direct food** refers to an import of GMOs or a combination of GMOs for human and animal consumption;
- 12. Import for processing product refers to an import of

GMOs or a combination of GMOs to process a product;

- 13. **Market introduction** refers to the supply of a product using GMOs as goods to the market;
- 14. **Intentional introduction into the environment** refers to the intentional introduction of GMOs which are not for limited use, or an import for direct consumption or processing;
- 15. **Release into nature** refers to an act of bringing GMOs into nature. This excludes limited use and import for direct food or product processing;
- 16. **Use for medicine** refers to the use of GMOs or a combination of GMOs for use in medicines;
- 17. **Measures** refers to the measures used for the inspection of any increase in biodiversity that is destroyed;
- 18. **Socio-economic impact** refers to a direct or indirect result of GMOs or Genetically Modified Products on socioeconomic conditions.

#### Article 4 State policy on biotechnology safety

The State pays attention to the management of safety in biotechnology to ensure the safety, limitations and reduction of risks to life, human health, animals, plants and the environment, with the aim of creating consumer confidence in biotechnological activities,

The State encourages and promotes safety in biotechnological works by providing a budget, building basic infrastructure, developing and contributing human resources, contributing equipment for research, development, utilization, and services in genetic resources in order to integrate with regional and international levels and to contribute to national socio-economic development.

The State promotes, protects, and disseminates research results and traditional knowledge in conjunction with the use of biotechnology.

#### Article 5 Principles on biotechnology safety works

Biotechnology safety works shall observe the following principles:

1. Ensure consistency with the national socio-economic

development plan, science and technology strategy, and the master plan on environmental protection;

- 2. Ensure equality before the law for biotechnological businesses;
- 3. Ensure safety, transparency, and fairness, and be open to inspection;
- 4. Ensure international standards are met by utilizing modern biotechnology;
- 5. Ensure consistency with international agreements and treaties on biotechnology safety to which Lao PDR is a party.

#### Article 6 Scope of application

This law is applied to individuals, legal entities, and domestic and international organizations working or operating in regard to biotechnology safety in the Lao PDR.

This law does not apply to medicines made from GMOs.

#### **Article 7 International cooperation**

The State promotes foreign, regional and international relations and cooperation on biotechnology safety by exchanging their experiences, information, news, techniques, technologies, scientific research, education, human resource development and donor assistance, and follows international agreements and treaties to which the Lao PDR is a party.

# Part II Biotechnological Works

# Section 1 Types of Research and Development

#### Article 8 Biotechnological research and development

Biotechnological research and development is the process of searching for a phenomena in natural law to serve as a scientific foundation on living organisms, and its application in socio-economic development, national defense and security, healthcare, environmental protection, and the sustainable use of genetic resources, including searching for a cause of and the management approach to reducing impacts from the use of biotechnology.

#### Article 9 Types of biotechnological research and development

There are three types of biotechnological research and development as follows:

- 1. Basic scientific research and development;
- 2. Applied scientific research and development;
- 3. Research on biotechnological risk.

#### Article 10 Basic scientific research and development

Basic scientific research and development refers to the use of modern biotechnology in modifying the dominant genetic characteristics of a species to implant into other species in order to create a new living organism in a laboratory.

# Article 11 Applied scientific research and development

Applied scientific research and development refers to the introduction of a new species toward performing tests on environmental safety, in order to process, and increase product value and modify based on socio-economic development needs.

# Article 12 Research on biotechnological risk

Research on biotechnological risk is the examination of risk factors related to GMOs which may have adverse impacts on conservation and sustainable use of biodiversity, with a focus on limiting and reducing risk to the life and health of human beings, animals, plants and the environment.

# Section 2 Research and Development

#### Article 13 Research and development priorities

Biotechnological research and development is a new, wide open field promoted for the conservation and sustainable use of genetic resources by defining research and development plans at the national level within priority areas that hold potential for socio-economic development as follows:

### 1. Biotechnology in genetic resources;

- 2. Biotechnology in agriculture and forestry;
- 3. Biotechnology in health;
- 4. Biotechnology in industrial processing;
- 5. Biotechnology in the environment.

# Article 14 Biotechnology in genetic resources

Areas of biotechnological research and development of genetic resources at the national level include the following:

- 1. Identification of characteristics and establishment of a genetic database;
- 2. In-situ conservation of genetic resources such as conservation forests and conservation areas;
- 3. Ex-situ conservation of genetic resources such as botanic gardens and community gardens;
- 4. Sustainable use of genetic resources;
- 5. Other topics based on the needs of socio-economic development periodically.

# Article 15 Biotechnology in agriculture and forestry

Areas of research and development of biotechnology in agriculture and forestry at the national level are as follows:

- 1. Plant variety development and improvement;
- 2. Animal breed development and improvement;
- 3. Soil and water resource development and improvement;
- 4. Forest resource development and improvement;
- 5. Other topics based on the needs of socio-economic development periodically.

# Article 16 Biotechnology in health

Areas of research and development of biotechnology in health at the national level are as follows:

1. Food and nutritional value;

2. Disease testing and diagnostics;

- 3. Development of traditional and modern medicine;
- 4. Disease prevention, treatment and health promotion;
- 5. Other topics based on the needs of socio-economic development periodically.

#### Article 17 Biotechnology in the processing industry

Areas of research and development of biotechnology in the processing industry at the national level are as follows:

- 1. Processing and value added products;
- 2. Packaging and trademarks;
- 3. Production standards and quality;
- 4. Bioenergy;
- 5. Other topics based on the needs of socio-economic development periodically.

#### Article 18 Biotechnology in the Environment

Areas of research and development of biotechnology in the environment at the national level are as follows:

- 1. Biological indicator of ecological systems;
- 2. Environmental quality control;
- 3. Management of waste and pollutants harmful to the environment;
- 4. Environment conservation and rehabilitation;
- 5. Other topics based on the needs of socio-economic development periodically.

#### Section 3 Use of Biotechnology

#### Article 19 Use of biotechnology

Use of biotechnology is the mobilization of successful results in biotechnology research and development as specified in Articles 14, 15, 16, 17 and 18 of this law.

#### Article 20 Types of biotechnology use

Types of biotechnology use are as follows: 1. Contained use for research and development;

- 2. Import for direct food or processing products;
- 3. Market introduction;
- 4. Intentional introduction into the environment;
- 5. Release into nature;
- 6. Use for medicine.

# Section 4 Protection of Research and Development Results

# Article 21 Biotechnology patents

Providing that biotechnology is associated with patents in other areas, the use and transfer of such rights is managed and protected as stipulated in the Law on Intellectual Property.

# Article 22 Traditional knowledge

Traditional knowledge is promoted and protected as follows:

- 1. Respect, protect and mobilize creativity and the actual practices of people that are related to conservation and sustainable use of genetic variation;
- 2. Extensive use by means of approval and promotion of creativity and skills with participation of the owners, and the benefits from knowledge, creativity and skills shall be properly shared;
- 3. Protect and encourage the use of genetic resources related to the traditional culture being practiced, consistent with the conservation and sustainable use of its contents;
- 4. Encourage and assist local populations to develop and implement measures on conservation and protection of rare areas of genetic diversity to avoid deterioration;
- 5. Encourage all public and private agencies to cooperate in conservation and the sustainable use of genetic resources.

# Article 23 Human cloning

Human cloning is biotechnology research in health by creating a genetically identical copy of a human being through transfer of the cell nucleus and genetic traits from one cell to other another cell. Research, development and strengthening the capacity of human cloning for the purpose of treatment by controlling cellular proliferation for developing human organs necessary for transplantation; such treatments shall be promoted and protected.

Human cloning for reproduction by creating a human body that has a soul is prohibited.

#### Article 24 Access to and benefit sharing of genetic resources

All parties can access to genetic resources by using such resources consistent with environmental conditions, conservation, and the sustainable use of genetic resources, and shall share the benefits of using such resources equally and legitimately, as well as being able to access the transfer of relevant biotechnology appropriately.

#### **Article 25 Confidential information**

Individual, legal entities or organizations shall keep the results of biotechnology and genetic engineering confidential in order to protect the rights and interests in trade and national security, unless otherwise stipulated in the law.

# Part III Biotechnology Risk Analysis

#### Article 26 Biotechnology risk analysis

Biotechnology risk analysis is the scientific process by which an assessment is made in the management and communication of information on location, geographical conditions, weather and ecological characteristics, including information on biodiversity and the origin of the GMO.

#### Article 27 Handling request and risk Analysis

Individual, legal entities or organizations whose objective is to operate businesses associated with GMOs shall submit a handling request to the National Committee for Biotechnology Safety for consideration.

Biotechnology risk analysis shall be carried out according to the following procedures:

1. Biotechnology risk assessment;

- 2. Biotechnology risk management;
- 3. Biotechnology risk communication.

# Article 28 Technical regulations on risk analysis

The National Committee for Biotechnology Safety shall collaborate with the relevant agencies to study and formulate technical regulations on risk analysis in developing and using GMOs.

# Section 1 Biotechnology Risk Assessment

# Article 29 Biotechnology risk assessment

Biotechnology risk assessment of GMOs or products made from such organisms is a direct or indirect assessment of scientific processes regarding risks on life, health, animals, plants and the environment, including socio-economic conditions and cultural values.

Risk assessment is carried out on a case by case basis according to changes in information which are necessary for the content and details of the GMO, or products made from such organisms for intentional use.

# Article 30 Risk assessment process

Risk assessment process shall proceed as follows:

- 1. Defining new genetic traits and characteristics shown by a GMO which may impact the diversity of genetic resources in the environment, where attention shall be paid to risk on life, human health, animals, plants and the environment;
- 2. Assessment of the living conditions of things that are expected to be affected by GMOs, with attention paid to rating and type of risk diversification in the environment;
- 3. Assessment of results caused by possible negative impacts;
- 4. Overall risk estimation of GMOs based on an assessment of living conditions and possible severe impacts;
- 5. Recommendations on risks, which shall specify whether they are acceptable or manageable, as well as an introduction of risk measures or management if necessary.

In cases of necessity that need additional information on an issue, the applicant shall provide such information on a case by case basis during the risk assessment.

# Article 31 Objectives of risk assessment

Risk assessment shall take into consideration the scientific details and techniques related to various characteristics with the objectives as below:

- Biological characteristics of organisms that receive genetic codes or donor cells, gather information about genetic classification conditions, general name, source of origin, center of genetic diversity and explanation of the living conditions of such organisms which can exist and grow;
- 2. Characteristics of genetic providers, including specific traits, source of origin and its habitat;
- 3. Genetic characteristics that are modified, including their roles and changes in patterns that occur;
- 4. Classification of GMOs and differences between the biological characteristics of GMOs and organisms targeted to receive genetic codes or donor cells;
- 5. Introduction of proof of method for GMOs and specific traits which certify explicitness;
- 6. Information on the intentional use of GMOs, including new uses or adaptation of organisms, and comparison with organism data targeted to receive genetic codes or donor cells;
- 7. Information related to location, geography, weather and ecological characteristics, including information on biodiversity and sources of GMOs in the environment.

# Section 2

# **Biotechnology Risk Management**

# Article 32 Biotechnology risk management

Biotechnology risk management is the use of the results of direct or indirect assessment through scientific processes related to risk to life, human health, animals, plants and the environment, for use as reference for administration and management of activities associated with GMOs.

# Article 33 Basic principles of risk management

Risk management shall be implemented according to primary principles as follows:

- 1. Create proper strategies, mechanisms and approaches in order to manage and examine risk related to obtaining the right of possession, use and cross-border movement of GMOs;
- 2. Formulate measures on risk assessment to prevent negative impacts of GMOs and the sustainable use of genetic resources, especially risk to life, human health, animals, plants and the environment;
- Apply proper measures to prevent unintentional cross-border movement of GMOs; risk assessment shall be conducted before the initial release of GMOs into nature is allowed;
- 4. Export and import of GMOs, or self-developed GMOs, shall go through a monitoring period over a life cycle period of the organism before using.

# Article 34 Approaches to risk assessment management

Approaches to risk assessment management shall proceed as follows:

- 1. The National Committee for Biotechnology Safety shall ensure that risk assessment is properly implemented, and such assessment shall cover all activities associated with GMOs;
- The Technical Coordination Committee shall assess risk as well as examine the results of risk assessment that is carried out based on scientific principles and risk assessment techniques;
- 3. The Technical Coordination Committee shall pay attention to all information shown on GMOs. Risk assessment shall be conducted based on the primary information specified in the application and other scientific information;

- 4. The Technical Coordination Committee shall inspect risk assessment, based on the application, that must be carried out, or incidents that lead to additional risk assessment on a case by case basis;
- 5. The Technical Coordination Committee shall pay attention to measures on risk assessment that the applicant requests, and additional risk assessment measures that need to be reduced. Providing that there is dissatisfaction with the assessment results, the applicant, the Technical Coordination Committee, or experts or consultants can proceed based on the agreement of the National Committee for Biotechnology Safety;
- 6. The Technical Coordination Committee shall summarize and report the results of risk assessment and its examination process to the National Committee for Biotechnology Safety by providing their opinions, as well as certify other necessary alternatives, in order to ensure safety in using GMOs;
- 7. The National Committee for Biotechnology Safety shall ensure the availability of proper mechanisms, measures and approaches to management, administration and inspection of the identified risks;
- 8. The National Committee for Biotechnology Safety shall provide risk assessment reports to the applicant and the Technical Coordination Committee within 30 days from the date of receiving the report onward;
- 9. The applicant shall provide comments on the report of the Technical Coordination Committee in writing within 30 days from the date of receiving the report, and such report shall be considered by the National Committee for Biotechnology Safety.

# Section 3 Biotechnology Risk Communication

#### Article 35 Biotechnology risk communication

Biotechnology risk communication is the use of risk assessment

and management results as reference for consideration and communication on the agreement results, agreement review, monitoring, providing new information, and proposals to issue an order to terminate businesses related to GMOs.

# Article 36 Agreement and communication on agreement results

Agreement and communication on agreement results shall proceed as follows:

- 1. After receiving a risk assessment report, the National Committee for Biotechnology Safety makes the final decision on granting protection rights as requested;
- 2. Agreements related to point 1 above shall be made on the basis of the following:
- a) Information provided in the application form;
- b) Risk assessment report by the Technical Coordination Committee;
- c) Written comments of the applicant;
- d) Comments from society.
- 3. For consideration, the National Committee for Biotechnology Safety shall pay attention to matters related to the international obligations of the Lao PDR and socio-economic issues;
- 4. Limited information on science, knowledge, and intelligence related to limiting the negative impacts of GMOs shall not hinder the assessment of the Technical Coordination Committee;
- 5. The National Committee for Biotechnology Safety shall consider and make the final decision, and then issue notice of the result to the applicant within 120 days from the date of submitting the request on importing GMOs onward. In addition to the purpose of introduction into the market, notice shall be issued within 270 from the date of submitting the request onward;
- 6. Regarding the final agreement of the National Committee for Biotechnology Safety, the contents of supporting documentation shall be recorded on the:

- a) Certification of application status and summary of content related to the application status;
- b) Explanation on the process of the application review;
- c) Conclusion of risk assessment;
- d) Notice of approval and rejection activities;
- e) Explanation of reasons for approval or rejection.
- 7. Individuals, legal entities or organizations have no right to change the objectives of their activities as agreed on unless approved by the National Committee for Biotechnology Safety;
- 8. The National Committee for Biotechnology Safety registers GMOs or management activities as specified in this law;
- 9. Individuals, legal entities or organizations have the right to submit proposals to the administrative organization in order to reconsider the rejection of the possession rights of GMOs, or revocation and withdrawal of such right. Relevant administrative organizations shall amend such proposals based on the regulations within 30 working days from the date of receiving the proposal onward.

# Article 37 Agreement revision

Agreement revision shall proceed as follows:

- 1. The National Committee for Biotechnology Safety can consult with the Technical Coordination Committee anytime upon receiving new scientific information, by paying attention to risk on life, animals, plants and the environment;
- 2. The National Committee for Biotechnology Safety shall notify the applicant about the target plan and the reasons for revision of the agreement;
- 3. The applicant can submit proposals to review the agreement to the National Committee for Biotechnology Safety when there is:
- a) Changes to conditions that create impacts;
- b) Additional scientific or technical information.
- 4. The National Committee for Biotechnology Safety shall have discussions with the Technical Coordination Committee according to the conditions of said changes which constitute

the cause or the main factors that can be verified and measured using a scientific approach.

5. The National Committee for Biotechnology Safety shall inform the applicant in writing, stating the reason(s), within ninety days from the day the petition is received.

# Article 38 Monitoring and provision of updated information

Monitoring and provision of updated information must be conducted as follows:

- 1. The concessionaire shall follow up on their activities that are relevant to the rights, obligations and terms stipulated in this law.
- 2. The concessionaire who has updated information, or any information that has not yet been considered, shall inform the National Committee for Biotechnology Safety.
- 3. The concessionaire shall provide confidential information to the National Committee for Biotechnology Safety as proposed.

# Article 39 Proposal of instructions

The National Committee for Biotechnology Safety shall propose to the Minister of Science and Technology to provide instructions according to each case as follows:

- 1. To cancel approved activities that can jeopardize the conservation and sustainable use of biodiversity, and the lives and health of human beings, animals and the environment.
- 2. To adopt additional measures for appraising risks from the aforementioned activities.
- 3. To immediately terminate activities in cases where it is found that the concessionaire commits any offence or fails to abide by the Law and regulations;
- 4. To terminate activities where reports are found to not be true in fact.

# Part IV Human Resource Development and Public Participation

#### Article 40 Human resource development

Human resource development in scientific and biotechnological areas shall be promoted and supported with education and training for the relevant sectors.

#### **Article 41 Specialists**

Specialists are scholars with skills in a specific area or graduated doctors with broad knowledge on a specific matter, and have rights and duties as follows:

- 1. To provide information with scientific and technological risk assessment reports concerning the conditions of genetic resources and their components;
- 2. To assess scientific and technological risks according to the methods defined in Article 34 of this law;
- 3. To certify optional measures and methods, efficiency and conditions of biotechnology, and knowledge regarding conservation and sustainable uses of genetic resources;
- 4. To advise in respect to the way to promote the development and passing on of technologies, scientific plans and international cooperation for research and development of conservation and sustainable uses of genetic resources.
- 5. To answer scientific, technical and technological questions;
- 6. To comply with other rights and duties stipulated in the Law and regulations.

#### **Article 42 Public participation**

Public participation in safety tasks related to transfer, preserve and using GMOs must be connected to the training so as to generate consciousness of conservation and sustainable uses of genetic resources, through expansive promotion and in order to prevent risks to the life and health of human beings, animals, plants and the environment.

# Article 43 Information exchange of researches

Relevant sectors shall exchange information regarding successes in scientific, technical, economic, cultural, and social research, and traditional knowledge concerning the conservation and sustainable use of genetic resources.

# Article 44 Biotechnology safety clearing house

Relevant sectors shall establish an biotechnology safety clearing house (BCH) to facilitate the information exchange of science, techniques, the environment, the Law and regulations, and experiences regarding the GMOs.

# Part V Prohibitions

# **Article 45 General prohibitions**

Individuals, juristic persons or organizations are prohibited from engaging in the following conduct:

- 1. Performing security tasks regarding biotechnology without permission;
- 2. Creating obstacle(s) that hinder the promotion and development of biotechnological safety;
- 3. Importing outdated biotechnologies and consuming natural resources as sources, taking risks to the life and health of human beings, animals, plants and the environment;
- 4. Counterfeiting, destroying or using counterfeit documents pertaining to biotechnology safety;
- 5. Engaging in other conduct that violates the Law and regulations.

# **Article 46 Prohibitions for Concerned Government Officials**

Prohibitions for concerned government officials are:

- 1. Exploiting power, duties or position to threaten others toward seeking personal and company benefit;
- 2. Pressing or asking for bribes or other benefits;
- 3. Disclosing national or governmental confidential information,

or secrets related to personal operating tasks concerning biotechnology safety;

- 4. Procrastinating or prolonging the time for considering documents re. biotechnology safety without good reason;
- 5. Counterfeiting, destroying or using counterfeit documents pertaining to biotechnology safety;
- 6. Other conduct that violates the Law and regulations.

#### **Article 47 Restrictions on entrepreneurs**

Entrepreneurs working on biotechnological safety are prohibited from the following:

- 1. Undertaking tasks that have not received permission;
- 2. Using one's own license as guarantee or form a partnership, for lending, leasing, transferring or selling to other parties;
- 3. Offering bribes to government or private officials;
- 4. Committing an act of violence or assuming another's name to threaten concerned governmental officials;
- 5. Counterfeiting, destroying or using counterfeit documents pertaining to bio-technological safety;
- 6. Any other conduct in violation of the Law and regulations.

# Part VI Dispute Resolution

#### 'Article 48 Forms of dispute resolution

Settlement of disputes shall be undertaken as follows:

- 1. Settlement through compromise;
- 2. Settlement by administrative means;
- 3. Settlement by the Office of Economic Dispute Resolution;
- 4. Bringing a suit to a court of justice;
- 5. Settlement in an international manner.

#### Article 49 Settlement through compromise

In case of a dispute over biotechnology safety, the two parties may settle the dispute through discussion or compromise in a mutually beneficial manner.

# Article 50 Settlement by administrative means

In case of a dispute over biotechnology safety pertaining to management under the responsibility of an administrative agency, the two sides have the right to submit such dispute to the aforementioned agency for resolution.

# Article 51 Settlement by the Office of economic dispute resolution

In case of an economic dispute over biotechnology safety, the two parties can submit such dispute to the Office of Economic Dispute Resolution for settlement as legislated in the Law concerning economic dispute resolution.

# Article 52 Bringing a suit to a court of justice

In case of a dispute over biotechnology safety, the two parties can sue at the people's court for adjudication according to Law and regulations.

# Article 53 Settlement by international arbitration

In case of a dispute over biotechnology safety by international arbitration, such dispute shall comply with international agreements and conventions to which the Lao PDR is a party.

# Part VII The Committee for Biotechnology Safety Administration

# Article 54 The Committee for Biotechnology Safety Administration

The Committee for Biotechnology Safety Administration consists of:

1. The National Committee for Biotechnology Safety

2. The Technical Coordination Committee

In cases where it is necessary, the Committee for Biotechnology Safety Administration may be established in local areas.

# Article 55 Location and functions of the National Committee for Biotechnology Safety

The National Committee for Biotechnology Safety is not an ad

hoc organization. This Committee has technical or academic functions and responsibilities for organizationally implementing tasks concerning biotechnology safety, and consists of representatives from ministries and organizations related to biotechnology and biotechnology safety.

# Article 56 Structure of the National Committee for Biotechnology Safety

The National Committee for Biotechnology Safety consists of:

- 1. Minister of the Ministry of Science and Technology as President;
- 2. Deputy Minister of the Ministry of Natural Resources and Environment as Vice president;
- 3. Deputy Minister of the Ministry of Agriculture and Forestry as Vice-president;
- 4. Deputy Minister of the Ministry of Public Health as committee member;
- 5. Deputy Minister of the Ministry of Science and Technology as committee member and Chief of the Technical Coordination Committee;
- 6. Other relevant Deputy Ministers as committee members.

The National Committee for Biotechnology Safety is authorized by the Prime Minister and maintains a Technical Coordination Committee as the secretariat at the Ministry of Science and Technology.

# Article 57 Rights and Duties of the National Committee for Biotechnology Safety

The National Committee for Biotechnology Safety has the rights and duties as follows:

- Improving or modifying conditions, standards, manuals and procedures of the Ministry of Science and Technology and other relevant ministries in the implementation of biotechnology risk analysis;
- 2. Giving instructions to the Technical Coordination Committee in terms of risk assessment, concessions, importation, transportation across borders, and limitations on usage upon

releasing into nature, and marketing;

- 3. Creating internal regulations and technical procedures concerning risk analysis;
- 4. Establishing an biosafety clearing house and facilitating public access to information regarding living things with modified genetic characteristics or products made from living things;
- 5. Promoting training, and raising consciousness and participation of people related to activities protected by this Law, including publishing manuals and other printing materials related to biotechnology safety tasks;
- 6. Establishing administrative mechanisms to ensure the appropriateness of concessions, distribution and filing of documents and information connecting to processes related to submitting applications, attached documents or other relevant materials;
- 7. Considering applications and proposing approval or cancellation re. concessions, importation, exportation, transportation across borders, contained uses, environmental release and marketing;
- 8. Summary reports on implementation shall be submitted to the Government regularly;
- 9. Performing other rights and duties as legislated in the Law and regulations.

# Article 58 Location and functions of the Technical Coordination Committee

The Technical Coordination Committee is an officially designated unit. It functions as the Chief of Staff and Secretariat of the National Committee for Biotechnology Safety and is authorized by the President of the National Committee for Biotechnology Safety.

# Article 59 Structure of the Technical Coordination Committee

The Technical Coordination Committee consists of:

- 1. Deputy Minister of the Ministry of Science and Technology as Head;
- 2. Director General of key concerned Department and Institute

as Deputy Heads;

- 3. Director General of other concerned Department and Institute as members;
- 4. Specialists from other concerned sectors as members;
- 5. Representatives from concerned organizations as members;
- 6. Various technical staff as assistants.

# Article 60 Rights and Duties of the Technical Coordination Committee

The Technical Coordination Committee has the rights and duties as follows:

- 1. Implementing and reviewing risk assessment;
- 2. Stipulating and reviewing risk management measures;
- 3. Creating mechanisms for reporting, proposing measures for the reduction of risks, and implementation of biotechnological safety;
- 4. Giving technological advice and examining applications submitted to the National Committee for Biotechnology Safety for consideration;
- 5. Reports on implementation shall be regularly submitted to the National Committee for Biotechnology Safety;
- 6. Performing other rights and duties as legislated in the Law and regulations.

# Part VIII Administration and Inspection

# Section 1 Administration of Biotechnology Safety Tasks

#### Article 61 Administrative organization

The Government is the administrative body controlling biotechnology safety tasks centrally, with unity throughout the country, by entrusting the Ministry of Science and Technology to be the owner and take direct responsibility, and collaborate with ministries, other organizations and local relevant authorities. The administrative organization controlling biotechnology safety tasks consists of:

- 1. The Ministry of Science and Technology;
- 2. The Department of Science and Technology at Capital and Provinces;

3. Science and Technology Office at District and Municipality. In cases where it is necessary, a Science and Technology Unit may be established in each village.

# Article 62 Rights and Duties of the Ministry of Science and Technology

In the management of biotechnology safety tasks, the Ministry of Science and Technology has the rights and duties as follows:

- 1. Researching, stipulating policies on biotechnologies and GMOs as a national action plan, the Law and regulations, technical instructions, plans and management, and monitoring projects in detail.
- 2. Organizationally implementing such management and monitoring, as well as reporting the conditions of biotechnologies and GMOs throughout the country.
- 3. Being the center for collaborating with sectors and local authorities, and researching and solving problems regarding biotechnologies and GMOs;
- 4. Giving instructions to development projects and activities concerning the provision of reports on biotechnologies and GMOs;
- 5. Following up on organizational implementation of the National Action Plan, the Law and regulations, technical instructions, plans, and exhaustive projects in terms of biotechnologies and GMOs;
- Granting permission to or withdrawing permission from any organizational service operations concerning biotechnologies and GMOs;
- Collaborating with concerned parties that are entitled to modify, pause, move or abolish any activity causing adverse impacts on biodiversity from the use of biotechnologies and GMOs;

- 8. Receiving and considering propositions of peoples and concerned persons on biotechnological safety and GMOs;
- 9. Discussing tasks related to biotechnologies and GMOs;
- 10. Constructing, increasing levels of knowledge for academic staff together with training, and raising consciousness on biotechnologies and GMOs in all sectors of society throughout the country by collaborating with the concerned sectors and local authorities;
- 11. Organizationally disseminating, summarizing and appraising the information system of biotechnologies and GMOs;
- 12. Coordinating and cooperating with international organizations working on biotechnologies and GMOs;
- 13. Summary reports on implementation of tasks of biotechnology safety shall be submitted to the government regularly;
- 14. Performing other rights and duties as stipulated under the Law and regulations.

# Article 63 Rights and Duties of the Department of Science and Technology at Capital and Provinces

In the management of tasks concerning biotechnology safety, the Department of Science and Technology at Capital and Provinces has the rights and duties under its areas of responsibility as follows:

- 1. Implementing the Law and regulations on biotechnology safety;
- 2. Creating and implementing plans on biotechnology and GMOs based on the integral plan of the Ministry of Science and Technology;
- 3. Researching and solving problems about biotechnology safety and GMOs related to their local areas;
- 4. Monitoring implementation of the Law and regulations related to their local divisions concerning biotechnology safety and GMOs;
- 5. Receiving and deliberating propositions from persons and parties related to their local divisions regarding biotechnology safety and GMOs, and submitting such propositions to the

Ministry of Science and Technology for consideration and settlement;

- Reporting, discussing and exchanging experiences regarding science and technology with the Ministry of Science and Technology and related sectors in their local divisions in order to solve problems related to biotechnology safety and GMOs;
- Building capacity and increasing levels of knowledge for technical staff working on science and technology, providing training, and raising awareness regarding biotechnology safety and GMOs for people and sectors;
- 8. Collecting data and summarizing and disseminating information regarding biotechnology safety and GMOs;
- 9. Coordinating and cooperating with international organizations working on biotechnologies and GMOs;
- 10. Summarized reports on implementation of tasks regarding biotechnology safety shall be submitted to the Ministry of Science and Technology and provincial governors, and the Mayor of Capital, regularly;
- 11. Performing other rights and duties as stipulated by Law and regulations;

# Article 64 Rights and Duties of District and Municipal Science and Technology Offices

In the management of tasks regarding biotechnology safety, the Science and Technology Office of Districts or Municipalities have the rights and duties under their areas of responsibility as follows:

- 1. Creating and implementing plans and procedures concerning biotechnology safety and GMOs in their districts and municipalities based on the plans and procedures of the Department of Science and Technology at Capital and provinces, to which they are attached;
- 2. Researching and solving problems about biotechnology and GMOs;
- 3. Monitoring implementation of the Law and regulations

concerning biotechnology and GMOs;

- 4. Receiving and deliberating propositions of persons and sectors in relation to biotechnological safety and GMOs, and submitting proposals to the Department of Science and Technology for consideration and settlement;
- 5. Discussing and exchanging experiences related to science and technology with provincial and Capital administration and inspection units, and with local authorities and other relevant offices so as to solve problems regarding biotechnologies and GMOs;
- 6. Providing training and creating consciousness and awareness regarding biotechnologies and GMOs for people and concerned parties;
- 7. Collecting data, summarizing, deliberating and disseminating information regarding biotechnology safety and GMOs;
- 8. Reports on the implementation of tasks related to biotechnology safety and GMOs shall be submitted to the Department of Science and Technology and Governors and heads of municipalities regularly;
- 9. Performing other rights and duties as stipulated in the Law and regulations and assigned by higher ranking authorities.

# Article 65 Rights and Duties of other Sectors

In the management of tasks regarding biotechnology safety, other sectors, such as Sectors of Natural Resources and the Environment, Agriculture and Forestry, Public health, Industry and Commerce, and Planning and Investment, have the rights and duties to collaborate and cooperate with Science and Technology Sector according to the functions within their areas of responsibility.

# Section 2 Inspection of Biotechnology Safety Tasks

#### **Article 66 Inspection Agency**

The Inspection Agency for biotechnology safety consists of:

1. The Internal Inspection Agency, which shall also manage works related to bio-technological safety as stipulated in Article 61 of this Law;

2. The External Inspection Agency, which includes the National Assembly, Government Inspection and Anti-corruption Authority, State Inspection Authority, Lao Front for National Construction, mass organizations and mass media, according to the relevant laws.

# **Article 67 Contents of inspection**

The monitoring of biotechnology safety means inspection of all activities related to administration; namely research, development, services and usage of biotechnologies and GMOs according to the Law and regulations, focusing on protection from risks that may have adverse impacts on the life and health of human beings, animals, plants and the environment.

# **Article 68 Elements of inspection**

Inspections consist of 3 elements as follows:

- 1. Normal inspection, which is the regular inspection implemented as planned and rigidly scheduled;
- 2. Inspection with notice, which is an unplanned inspection when deemed necessary; the target of such inspection shall be informed in advance;
- 3. Sudden inspection, which is an urgent inspection, and where the target of the inspection is not informed in advance.

The inspection of tasks related to biotechnology safety shall be performed properly and strictly according to the Law and regulations.

# Part IX

# Policies on Performance Generators and Measures for Violators

#### Article 69 Policies on performance generators

Persons, juristic persons or organizations who conscientiously contribute to the tasks of research and development and usage of biotechnologies in socio economic development and environmental preservation will be praised or rewarded through other policies according to the regulations.

#### Article 70 Measures on violators

Persons, juristic persons or organizations that violate this Law or regulations related to biotechnological safety will be reprimanded, warned, punished, fined, or shall compensate for the damage or crime, with a light or heavy penalty accordingly.

# Article 71 Measures of reprimand

Persons, juristic persons or organizations who violate this Law or regulations related to biotechnology safety by committing minor offenses will be reprimanded or warned accordingly.

#### Article 72 Measures of punishment

An official who violates this Law by infringing a prohibition which is not a criminal offense, causing damage of low value or unfaithfully reporting, will be punished based on each case as follows:

- 1. Such official will be warned about the offense according to the Law and regulations concerning civil servants, and this shall be recorded in their personal record;
- 2. Promotion, salary raise, or praise for such official will be suspended;
- 3. Such official will be discharged or moved to a lower position;
- 4. Such official will be dismissed from the government without any benefits.

Those who receive punishment shall return any assets obtained illegally to the organization in full.

#### **Article 73 Measures of fines**

Persons, juristic persons or organizations shall be fined according to the following cases:

- 1. Those who do not respond heedfully after receiving a warning or reprimand;
- 2. Those who cause negative impacts or damage to preservation and the sustainable use of biodiversity;

- 3. Those who degrade environmental quality over the level stipulated by standards;
- 4. Those who research, develop, serve or use GMOs improperly, destroying the life and health of human beings, animals, plants and the environment;
- 5. Those who fail to comply with stipulations in the report on risk assessment of GMOs;
- 6. Those who deny or refuse to cooperate with relevant government officials;

The rates of such fines shall be decided in a separate procedure;

#### Article 74 Civil measures

Persons, juristic persons or organizations that violate this Law and regulations concerning biotechnological safety which cause damage to state or collective or individual property will be responsible for compensation of the damage they cause.

#### **Article 75 Criminal measures**

Any person who violates this Law and regulations concerning biotechnology safety which are considered criminal offenses shall be punished according to criminal law, dependent upon the severity of the crime.

#### Article 76 Measures of additional punishment

Aside from the main punishment as stated in Article 75 of this Law, the offender will receive additional punishment, such as suspension, withdrawal of license or termination of business, and confiscation of vehicles/materials used for committing such offense.

# Part X Final Provisions

#### Article 77 Organizational implementation

The Government of the Lao People's Democratic Republic is the executor of this Law.

#### Article 78 Effective date

This Law is effective from the date the Presidential Decree is issued and promulgated by the President of the Lao People's Democratic Republic, and fifteen days after the Official Chronicle is recorded.

Any provisions or articles contrary to this Law are nullified.

#### President of the National Assembly

Pany YATHOTOU

ໃບອະນຸຍາດເລກທີ: 93 /ກຍ.ກອກ ພິມທີ່ ເກົ້າຍອດ ອີເມດຈ໌ ພິມຄັ້ງທີ I ຈຳນວນ 1000 ຫົວ

ສະໜັບສະໜູນໂດຍ:

